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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,075	07/29/2003	Dwight H. Warkentin	P-9003.00	5951

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MEDTRONIC, INC.  
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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/629,075	WARKENTIN, DWIGHT H.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/24/04</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to because Fig. 6 refers to a non-existent Fig. 8 in boxes 610 and 616. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities: the serial numbers of the applications referred to in paragraphs 0002 and 0012 must be either supplied and/or updated to reflect their current status. Paragraph 0067 refers to a non-existent Fig. 7.

Appropriate correction is required.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the coupling of the absolute pressure sensor to an ambient pressure reference unit (claim 2) cannot be found.

***Claim Objections***

4. Claims 1, 8 and 17 are objected to because of the following informalities: in claim 1, the phrase "...corresponding to..." on the last line of step (e) appears to be a typographical error and should be deleted; in apparatus claims 8 and 17, the phrase "...the initial step..." (line 13) lacks antecedent basis. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear if it was the applicant's intent to include pacing and defibrillation leads as a part of the invention. If so, said leads should first be positively recited (e.g., "An apparatus according to claim 8, further comprising a pacing lead; wherein said pressure sensor is coupled to the pacing lead."). If this was not the intent of the applicant, then the phrase "adapted to be" should be inserted after the word "is" so that the leads are only functionally referred to. The examiner will assume the later condition when acting on the merits.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 4, 6-8, 10, 11, 13-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlson (Pat. No. 6,026,324).

Regarding claim 1 and claims with similar limitations, note col. 7.

Regarding claim 11, the examiner considers a pressure sensor located within the housing in its broadest sense to be coupled to pacing leads (22, 24) extending from the housing.

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Regarding claim 17, in order for the microprocessor-based controller of Carlson to operate, it is essential and thus inherent that the instructions be stored on a computer readable media.

***Claim Rejections - 35 USC § 102/103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 9 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carlson.

Although Carlson does not explicitly refer to the pressure sensor as an absolute pressure sensor, what constitutes an absolute pressure sensor may depend on how the signal is processed. The present claims do not require that the absolute pressure be actually measured, simply that the sensor is an absolute pressure sensor. By analogy, one could call a thermocouple a heat sensor even though its purpose in a given circuit may not be to sense heat, but rather to generate electricity. Therefore, the sensor of Carlson is considered capable of being an absolute pressure sensor. Furthermore, the accelerometer sensor disclosed by Carlson would not appear to be affected by ambient pressure, and therefore is inherently considered to be an absolute pressure sensor. In any event, the applicant gives no criticality to the use of such a sensor. It would appear that any sensor capable of accurately determining relative pressure changes during the iterative interval optimization test would be suitable for the task.

***Claim Rejections - 35 USC § 103***

10. Claims 2, 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson (Pat. No. 6,026,324).

Regarding claim 2, Carlson does not explicitly discuss the use of an absolute pressure sensor coupled to an ambient pressure reference unit. It is disclosed,

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however, that prior artisans have employed a wide variety of pressure sensors in the attempt to maximize cardiac output (see "Discussion of Related Art," col. 1). The applicant fails to give any criticality to the use of absolute pressure measurements. Furthermore, as stated above in the rejection of claims 9 and 19, it would appear that any sensor or sensor arrangement capable of accurately determining relative pressure changes during the iterative interval optimization test would be suitable for the task.

Regarding claims 5 and 12, although Carlson does not explicitly state that the pressure sensor is adapted to be coupled to a defibrillation lead, combined pacemaker/defibrillator implants are old and widely used to treat a combination of cardiac arrhythmias. To combine the Carlson pacemaker with a defibrillator in order to provide the most comprehensive and effective treatment would have been seen as an obvious matter of design with the condition of the individual under treatment dictating the need. It should be noted that in the broadest sense, a pressure sensor contained in an implant housing is considered to be coupled to any lead extending from the housing.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

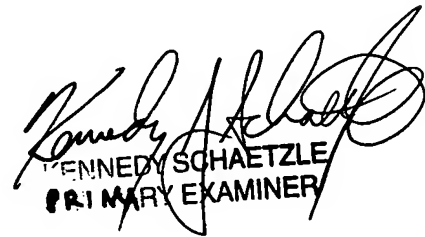
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
January 8, 2005



KENNEDY SCHAEETZLE  
PRIMARY EXAMINER